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Title: Chronic Heart Failure: Different Treatment Methods and Their Outcomes

Short title: Heart failure

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Abstract:
Chronic heart failure (CHF) remains one of the most important problems in cardiology, despite the availability of various modern diagnostic methods and a number of advances in treatment. This is due to its widespread use, lowering the quality of life of patients, as well as high rates of recurrent decompensation and death. Despite the optimal use of modern treatments based on proven medical principles, the disease still has a high morbidity and mortality rate (5,6,7,9,10).
The aims: The aim of our study was to evaluate the efficacy (activity, BNP levels, etc.) of a pathogenetically complementary conservative treatment with the inclusion of saccubitrile / valsartan in the treatment of patients with chronic heart failure in comparison with device-based CRT.

Materials and methods: The study included 64 patients over the age of 38 suffering from chronic heart failure (CHF). (45 men, 19 women, 59.5 ± 0.9 years of age). Patients were divided into basic and control groups. 33 patients were included in the main group. In the main group, patients received sacubitril / valsartan twice daily in addition to the classic conservative treatment of CHF. The control group included 31 patients who underwent CRT surgery. During the study, the clinical performance of patients before and after 6 months of treatment, the results of BNP tests, the results of a 6-minute walking test and EcoKG were compared.

Conclusion: Evaluation of the results of examinations of patients after 6 months revealed positive changes in the clinical indicators of the majority of patients in both groups compared to 6 months ago. However, better results were obtained in the main group than in the control group.

Keywords: CHF, BNP, sacubitril/valsartan, CRT

Introduction: In the treatment of patients with CHF, our main goal is to improve the clinical condition of patients, increase their functional capacity and quality of life, prevent re-hospitalization and, most importantly, reduce the number of deaths (1,8,11,12).

Many new drugs and devices are currently being used to treat patients with chronic heart failure. (2)

Modern principles of existing pharmacological treatments are based on the pathogenetic concept of CHF, which develops as a result of long-term activation of the neurohumoral system. These include, first of all, renin-angiotensin-aldosterenone and sympathetic-adrenal systems, which

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are considered pathognomonic in patients with chronic heart failure with poor prognosis. Theoretically, the combined use of different groups of neurohumoral modulators may provide additional benefits in the treatment of patients with chronic heart failure as a result of a more complete blockade of neurohormones. The essence of such a concept is very simple, so the higher the level of different levels of neurohumoral regulation, the better the result (2)

In recent years, a new pharmacological drug has been used in the conservative treatment of patients with chronic heart failure with a reduced emission fraction. This pharmacological drug is a pharmacological agent that can provide simultaneous blockade of both the angiotensin system and neprilisyn. Recently, a number of studies have been conducted on this drug, and a series of studies are ongoing.

In addition to drug treatment, the device is widely used in modern therapies. Of these, resynchron heart therapy is the most widely used treatment in recent years in all countries of the world.s

In patients with moderate to severe heart failure, CRT treatment may improve quality of life in two-thirds of patients and prolong life in one-third (11)

However, not all patients receiving this treatment respond positively to the CRT method. A number of features can affect the course of the disease after this treatment and the mortality rate. For example, in patients with ischemic etiology, left ventricular function develops less positively after this treatment due to scar tissue of the myocardium. This reduces the likelihood of favorable remodeling during the use of CRT in such patients.(3)

In previous years, according to the guidelines of the European Society of Cardiology, in patients preparing for implantation of a sinus rhythm SRT device, a QRS width of more than 130 ms could be considered a SRT (11). However, a number of studies published in recent years in 2018-2019, as well as the recommendations of the American Heart Association for 2018, require that this figure be strictly higher than 150 ms. (4)

Materials and methods

The study included 64 patients over the age of 38 who were treated at the Eurasia Hospital with a diagnosis of CHF. The diagnosis of CHF was confirmed on the basis of anamnesis, objective and instrumental examination methods.

Eligibility criteria: history of chronic heart failure; circulatory failure (functional class II-IV, NHYA); left ventricular ejection fraction <40%.

Exclusion criteria: acute myocardial infarction; hypertrophic cardiomyopathy; congenital heart defects; Patients under 25 years of age; heart failure in oncology patients.

According to the admission criteria, a total of 64 patients were included in the study, 45 men (70.3% ± 5.7%) and 19 women (29.7% ± 5.7%). The mean age of the patients was 59.5 ± 0.9. Of the 64 patients, 3 (4.7%) had 2nd f.c., 54 (84.4%) had 3rd f.c., and 7 (10.9%) had IV f.c. suffers from CHF. Figur 1.

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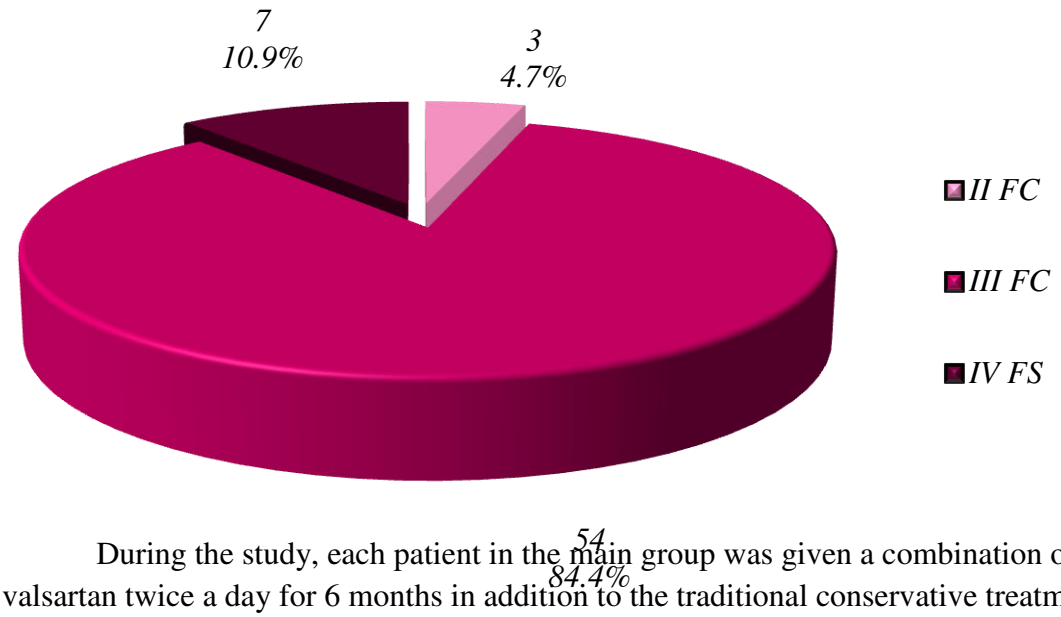
Figur 1.



During the study, each patient in the main group was given a combination of saccubitril / valsartan twice a day for 6 months in addition to the traditional conservative treatment of CHF (antiarrhythmic, hypolipidemic, anticoagulant, diuretic, hypotensive). Patients in the control group underwent CRT surgery in addition to receiving classic conservative treatment (excluding sakubitril / valsartan). Demographic and clinical characteristics of the patients included in the study are given in Table 1.

Table 1

Demographic and clinical characteristics of patients

Characteristics		Groups		p_U
		I group (n=33)	II group (n=31)	
Age, years		59,6±1,3 (38-70)	59,5±1,4 (39-73)	0,909
Sex	Male	25 75,8%	20 64,5%	0,329
	Female	8 24,2%	11 35,5%	
BMİ, kq/m^2		36,9±0,5 (31,6-43,6)	35,9±0,3 (32,1-38,7)	0,375
Obesity	I grade II grade III grade	8 24,2±7,5% 18 54,5±8,7% 7 21,2 ±7,1%	6 19,4±7,1% 25 80,6±7,1% –	0,310
Action	Active Inactive	4 12,1±5,7% 29	4 12,9±6,0% 27	0,925

		87,9±5,7%	87,1±6,0%	
Smoking	Doesn"t smoke Less Smoking Smoking a lot	8 24,2±7,5% 8 24,2±7,5% 17 51,5±8,7%	11 35,5±8,6% 4 12,9±6,0% 16 51,6±9,0%	0,685
Diabetus mellitus		27 81,8±6,7%	26 83,9±6,6%	0,829
Arterial hypertension		21 63,6±8,4%	20 64,5±8,6%	0,942
Family	Mother Fother Both	5 152%±6,2% 8 242%±7,5% 20 606%±8,5%	7 22,6±7,5% 4 12,9±6,0% 20 64,5±8,6%	0,975
Circulatory failure; NYHA	II FC III FC IV FC	2 6,1±4,2% 27 81,8±6,7% 4 12,1±5,7%	1 3,2±3,2% 27 87,1±6,0% 3 9,7±5,3%	0,983

Note: The difference between the groups is not statistically significant.

The differences between the study groups were not statistically significant. Thus, for all indicators it was p> 0.05. Clinical findings of patients before and 6 months after treatment (anamnestic data, SAH and DAH, pulse rate and fullness, physical examination), duration of initial compensation in both groups and the number of recurrent decompensations, SaO_2, BNP analysis results, results of the 6-minute walking test and EcoKG were evaluated comparatively. Statistical analysis included variance analysis (ANOVA Test), Wilcoxon Signed Ranks test, Cross analysis (Pearson Chi-Square Test) and Mann-Whitney test.

Table 2

Ranks	Pf	Pu	Px^2	Pw	
				Gr1	Gr2
Shortness of breath		0,890	0.990		
Shortness of breath a		0,012	0.043	<0.001	<0.001
Heartbeat		0,325	0.107		
Heartbeat a		0,298	0.076	<0.001	<0.001
Cough		0,713	0.068		
Cough a		0,021	0.063	<0.001	0.001
pulmonary auscultation		0,056	0.054		

pulmonary auscultation a		0,707	0.170	<0.001	<0.001
edema in the legs		0,399	0.395		
edema in the legs a		<0.001	0.001	<0.001	<0.001
Pulse fullness		0,877	0.876		
Pulse fullness a		0,424	0.420	0.317	0.046
Pulse rate	0.921	0,845			
Pulse rate a	0.931	0,772		<0.001	<0.001
SaO_2	0.104	0,138			
SaO_2 a	0.325	0,439		<0.001	<0.001
QRS	0.583	0,655			
Decompentation	0.579	0,373			
Decompentation a	0.668	0,859		<0.001	<0.001
BNP	0.766	0.687			
BNP a	0.000	0.000		<0.001	<0.001
6 min. walk test		0,189	0.185		
6 min. walk test a		0,002	0.001	<0.001	<0.001
FC		0,983	0.813		
FC a		0,017	0.083	<0.001	<0.001
Initial compensation period		0,050	0.065		
SAH	0.460	0,620			
SAH a	0.529	0,937		<0.001	<0.001
DAH	0.526	0,718			
DAH a	0.567	0,573		<0.001	<0.001

Table 3

ExoKG indicators of groups

Sings.	Groups	Count	M	±m	min	max	p_F	p_U	p_W
ESD	Group 1	33	41,4	0,9	33	50	0,158	0,068	
	Group 2	31	43,3	0,9	30	55			
ESD a	Group 1	33	39,8	1,0	32	50	0,010	0,006	< 0,001
	Group 2	31	43,5	1,0	29	56			0,197
EDD	Group 1	33	60,5	0,5	57	66	0,161	0,133	
	Group 2	31	61,6	0,6	55	67			
EDD a	Group 1	33	58,3	0,6	53	66	< 0,001	0,001	< 0,001
	Group 2	31	61,8	0,7	55	67			0,142
EFL W	Group 1	33	26.9	0.9	15	33	0.957	0.651	
	Group 2	31	26.8	1.1	15	38			
EFL W a	Group 1	33	32.8	1.1	20	44	0.257	0.184	< 0,001
	Group 2	31	31.0	1.2	19	45			< 0,001
EAD	Group 1	33	39.2	0.7	32	51	0.056	0.055	

	Group 2	31	41.0	0.7	34	52			
SPAh	Group 1	33	28.8	1.1	20	41	0.824	0.951	
	Group 2	31	29.1	0.8	23	40			
SPAH	Group 1	33	26.5	0.9	18	39	0.158	0.354	0.001
a	Group 2	31	28.1	0.6	23	36			0.002

Discussion:

As can be seen from the tables below, all patients' pulse and blood pressure, anamnesis, physical examination results, 6-minute walking test results, as well as EcoGq results, and B-type natriuretic peptide levels in the blood were examined in detail by statistical analysis. Both qualitative and quantitative tests were used in statistical analysis.

During the Wilxson test, statistically significant differences were obtained in the results of other indicators after 6 months, except for pulse saturation in group 1. P <0.05. The calculation of pulse saturation results before and after 6 months did not make a statistically significant difference (p = 0.317). There are also positive changes in the comparison of pre- and post-treatment outcomes of patients in group 2. Thus, statistically significant changes were obtained on most indicators during the statistical analysis in this group as well. P <0.05. Only the Echocardiogram did not show a statistically significant difference in the size of the left ventricle before and after 6 months. P=0.197, P=0.142. However, in this group there was a statistically significant difference in the results of LVEF. P <0.001. That is, positive results were obtained from the treatments performed in both groups separately. 6 months later intergroup analysis of patients' results was performed with the Mann-Whitney Test, ANOVA Test, and Pearson Chi-Square Test. Although these analyzes did not show statistically significant differences in all indicators, statistically significant changes were obtained in some indicators (history of shortness of breath, cough, lower peripheral edema during physical examination, number of recurrent decompensations, etc.) as shown in Table 2. The most important of these were BNP levels in blood, initial compensation period, 6-minute walking test and echocardiography. In the intergroup analyzes, the Mann-Whitney test showed statistically significant differences in BNP levels, initial compensation duration, 6-minute walking test and some EcoGq indicators (table 2 and 3). P <0.001, P=0.50, P=0.002, P=0.006, P=0.001. The Pearson Chi-Square Test, a qualitative analysis, did not show a statistically significant difference in most indicators, in the initial compensation period either (p=0.065). However, a statistically significant difference was obtained in the indicators of 6-minute walking test. P=0.001. Although the ANOVA test, a dispersion analysis, did not show statistically significant differences in other parameters, a statistically significant difference was obtained in BNP and left ventricular remodeling (ESD and EDD). p=0.000, p=0.010, p<0.001.

Conclusion:

1. We concluded that the addition of saccubitrile / valsartan complex to the treatment of patients led to a decrease in the level of BNP in the blood of patients to lower levels and, consequently, to further regulation of the pathogenetic system.

2. Repeated Echocardiography of patients showed a positive dynamics in the process of remodeling of the left ventricle in the main group.

3. The 6-minute walking test proved to have a better effect on patients' mobility than other treatments.

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